

Message

From: Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]
Sent: 2/16/2017 7:30:41 PM
To: McNally, Robert [McNally.Robert@epa.gov]
Subject: FW: Oxitec -- next steps

Bob – just making sure you saw this. I’m at Ex. 6 - Personal Privacy if we should talk.
Ritu

From: Nalubola, Ritu
Sent: Thursday, February 16, 2017 10:55 AM
To: McNally, Robert (McNally.Robert@epa.gov)
Subject: Oxitec -- next steps

Bob – Thanks for your patience as I figure out our group thinking here! So, the main reason a joint call was being proposed is that there are nuances with FDA-specific options that would be best and most accurately conveyed by FDA folks and/or in FDA presence. I didn’t necessarily read your note as EPA communicating FDA-specific info to the firm but something in the list of tentative TPs seems to have suggested that. Also, as I mentioned, we would like to steer the firm away from simultaneously seeking an INAD with FDA as well as an EUP with EPA – we’d like to nudge them the EUP route first and discuss INAD only if firm continues to be interested.

Either way, here’s what we came up with – please see if this works for you.

For purposes of the preliminary EPA and FDA separate calls to the firm, here’s what I see as key messages to be delivered:

Ex. 5 - Deliberative Process

Hope this makes sense. Once you agree, I’ll share with our group and loop you. Thanks!
If we should talk, please let me know a time and I can call you.
Ritu

From: McNally, Robert [mailto:McNally.Robert@epa.gov]
Sent: Wednesday, February 15, 2017 9:11 PM

To: Nalubola, Ritu
Subject: Re: Notes from Ostroff briefing

Thanks for the help. I appreciate it.

Bob

Sent from my iPhone

On Feb 15, 2017, at 8:56 PM, Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov> wrote:

Yes. And i'll get us on one page on our side. Let's just proceed the way we decided earlier in the evening
-- Draft TPs tomorrow and do separate calls on Friday w/ a goal for later joint mtg.

I will let you know if any changes tomorrow. Thx!
Ritu

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: McNally, Robert
Sent: Wednesday, February 15, 2017 8:47 PM
To: Nalubola, Ritu
Subject: Fwd: Notes from Ostroff briefing

I think it might be good for you all to figure out how FDA wants to proceed. I feel like there may be various views there and I would like just one.

I think EPA -- all of EPA -- has a firm enough sense of how they could proceed with us to tell them this week in a short phone call, pending a meeting next week.

My concern with waiting, along with waiting itself, is we have maybe 12-15 people from FDA and EPA in room or worse yet, in room and on phone, not knowing when someone might chime in with a different view, albeit only slightly.

Does this make sense?

Thanks

Bob

Sent from my iPhone